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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,893

02/24/2004

Jan K. Voda

1001.1889101

1262

28075 7590 09/25/2009
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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,893	Applicant(s) VODA, JAN K.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-36 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-36 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office Action following the Request for Continued Examination based on the 10/786893 application filed February 24, 2004. Claims 28-36 and 44-46 as amended and presented with the Request for Continued Examination on December 17, 2008 are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 33 and its dependents (34-36) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 33 discusses the catheter in terms of its “natural state” outside the patient, in relation to various planes of the patient. The examiner notes that although these terms are descriptive, they are not definite, nor do they further limit the device as they describe only its orientation relative to the patient and have no positive definition in the absence of a patient.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0103474 A1 to Voda.

Regarding the above claims, Voda discloses a steerable catheter (2) comprising a proximal shaft (4) having a long axis (not shown); and a distal shaft (8) extending from the proximal shaft, the distal shaft including: a preformed support section (10) including a transition segment (12) extending from the proximal shaft and an abutment segment (14) extending from the transition segment, wherein a portion of the proximal shaft adjacent to the distal shaft, the transition segment, and the abutment segment generally define a first plane (24) and the portion of the proximal shaft and the abutment segment are generally parallel (Fig. 1); and a preformed ostium entry section (16) comprising a first ostium segment (18) extending from the abutment segment and a second ostium segment (20) extending from the first ostium segment at a point of connection (indicated generally by angle $\alpha(d)$ in Fig. 1); and a distal tip (22) of the second ostium segment wherein the abutment segment and the point of connection define a second plane not coincident with the first plane (26), wherein the three dimensional steerable catheter has a first configuration (Fig. 1) and a second configuration (after rotation described in Paragraph [0023]), which configurations differ in the angle between the first plane and the second plane, further wherein the proximal shaft is rotated about the long axis [0023] and the abutment segment rests at least in part against an obstruction, the configuration of the three dimensional steerable catheter changes from the first to the second configuration and the distal tip follows the second plane as it rotates in response

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to rotation of the proximal shaft (the examiner has determined that this is accomplished based on the direction of rotation of the shaft and therefore the device of Voda would fulfill this limitation if rotated properly).

Furthermore, Figure 4 of Voda is identical to Figure 4 of the instant application showing catheter placement within the body of the patient, therefore Voda discloses a catheter wherein the abutment segment abuts an interior surface of the patient's ascending aorta in a plane formed by a tangent of an axis of the first segment when the distal tip is positioned within the ostium of the right coronary artery, wherein the second segment is coaxial to an axis of the right coronary artery when the distal tip is positioned within the ostium of the right coronary artery, and wherein the abutment segment is positioned at least about 5 millimeters above the level of the ostium of the right coronary artery when the distal tip is positioned within the ostium of the right coronary artery. Further, Voda discloses that the transition segment is twisted relative to the proximal shaft [0023].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 33-36 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voda.

Regarding the above claims, Voda discloses ranges for the angles between segments and lengths of segments that are substantially the same of the ranges of angles and segment lengths of the instant application, with the exception of $\alpha(f)$ (See [0014]-[0018] and [0020]). Voda also fails to specifically disclose a second segment that extends back toward a sagittal plane of the patient, however, this difference results from a change in the range of $\alpha(f)$ to 0-90 degrees in the instant application from 120-180 degrees in Voda. It is the examiner's position that it would have been obvious to one having ordinary skill in the art to modify the catheter previously disclosed by Voda to be produced in the range of angles and segment lengths disclosed by applicant, notably $\alpha(f)$, because there are a limited number of angles at which the $\alpha(f)$ could be positioned and it would not be beyond the scope of reasonable experimentation to produce catheters of varying $\alpha(f)$ angles to determine whether they were better received in the ostium of the right coronary artery.

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Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 28-36 and 44-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No.

6,595,983 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the patent above are drawn to essentially the same and invention, having a proximal shaft and a distal shaft comprised of a preformed support section and a preformed ostium entry section, having only different phrases and wordings in the claims and a single change of angle described in the rejection above to distinguish the inventions. It is well within the realm of obviousness to one having ordinary skill in the art to modify a single angle in a three dimensional catheter as described above.

Response to Arguments

11. Applicant's arguments filed December 17, 2008 have been fully considered but they are not persuasive.

12. Regarding applicants argument that the catheter of the pending claims provides torsionally variable geometry which allows the configuration to be altered by rotation of the proximal end of the catheter so that the tip may be directed to ostia which differ in location from that assumed by the design of Voda, the examiner notes the Voda provides a catheter having torsionally variable geometry [0028] and that altering an existing invention to simply fit into various internal geometries is an obvious modification to one having ordinary skill in the art as disclosed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763